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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
135,685	03/31/80	Saul W. Brusilow et al.	JHC-1031

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EXAMINER	
Cacciapaglia	
ART UNIT	PAPER NUMBER
125	MAILED
DATE MAILED:	

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

JUN 17 1980

GROUP 120

☒ This application has been examined. ☒ Responsive to communication filed on 3/31 & 5/14/80 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s),        days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited, Form PTO-892.
- ☐ Notice of Informal Patent Drawing, PTO-948.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

- ☒ Claims 1-10 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☐ Claims \_\_\_\_\_ have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 1-10 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☐ The formal drawings filed on \_\_\_\_\_ are acceptable.
- ☐ The drawing correction request filed on \_\_\_\_\_ has been ☐ approved. ☐ disapproved.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has  
☐ been received. ☐ not been received. ☐ been filed in parent application, serial no. \_\_\_\_\_,  
filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

Brusilow 135,685

A process for controlling waste nitrogen accumulation diseases in humans, caused by an impairment in the synthesis of urea from ordinary waste nitrogen in the body or in the excretion thereof, said process comprising administering an effective amount of at least one compound selected from the group consisting of benzoic acid, phenylacetic acid and the non-toxic, pharmaceutically-acceptable salts of said acids to a human suffering from such waste nitrogen accumulation disease, the amount of compound used being sufficient to react with the waste nitrogen to form an amino acid acylation product for urinary discharge of said product.

PART III (a)

SERIAL  
NUMBER

135685

GROUP ART UNIT  
125

## NOTIFICATION OF REJECTION(S) AND/OR OBJECTION(S) (35 USC 132)

	CLAIMS (1)	REASONS FOR REJECTION (2)	REFERENCES * (3)	INFORMATION IDENTIFICATION AND COMMENTS (4)
1	1-10	35 USC 112		Cl 1 fails to specify administration to a diseased host for treatment of a specific purpose and what the "effective amount" is effective for. "Suffering" (see par. 5)
		2nd par.		
2	1-10	35 USC 103	R, S, T, U, V, & W	R teaches administration of Na Benzoate to man and conversion to urinary hippuric acid; that normal urea and $\text{NH}_3$ -N content of urine is lowered as a result. (see par. 6)
3				
4				

- 5 from waste nitrogen accumulation" is not deemed always to involve a disease condition requiring treatment, there being a continual normal natural accumulation before voiding.
- 6 Cl 8 does not patentably distinguish from cl 1. moreover "discharged as urinary nitrogen" cl 3, 8, 10 appears mis-descriptive, the synthesized compounds being excreted as such. Cl 10 is indefinite, stating only a desired result without reciting the requisite steps.
- 6 S teaches marked increase of urinary-N (hippuric acid) after administration of benzoic acid in pigs. (See par 5, pg 3)

\* Capital letters representing references are identified on accompanying Form PTO-892  
 The symbol "v" between letters represents - in view of -.  
 The symbol "+" or "&" between letters represents - and -.  
 A slash "/" between letters represents the alternative - or -.

NOTE: Sections 100, 101, 102, 103, and 112 of the Patent Statute (Title 35 of the United States Code) are reproduced on the back of this sheet.

EXAMINER

F. CACCIAPAGLIA, JR.

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(703) - 557 - 2575

*F. Cacciapaglia*  
 Primary Examiner  
 Art Unit 125

**35 U.S.C. 100. Definitions.** When used in this title unless the context otherwise indicates —

- (a) The term "invention" means invention or discovery.
- (b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.
- (c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.
- (d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

**35 U.S.C. 101. Inventions patentable.** Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.** A person shall be entitled to a patent unless —

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

**35 U.S.C. 103. Conditions for patentability; non-obvious subject matter.** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**35 U.S.C. 112. Specification.** The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

PART III (a)

SERIAL  
NUMBER 135685GROUP ART UNIT  
125

## NOTIFICATION OF REJECTION(S) AND/OR OBJECTION(S) (35 USC 132)

	CLAIMS (1)	REASONS FOR REJECTION (2)	REFERENCES * (3)	INFORMATION IDENTIFICATION AND COMMENTS (4)
1				
2				
3				
4				

- 5 (cont'd from pg 2, par. 6) T and U teach administration of phenylacetic acid, respectively, to rabbits and man, the latter reference showing urinary glutamine conjugates. V and W are cumulative as showing affinity of applicants' compounds for systemic nitrogen in vivo in humans. To administer said compounds where it is desired to lower systemic nitrogen is obvious as is the employment of same for treatment of the enumerated diseases.

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3 of 3

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- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

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An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.